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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte STALEY BROD

Appeal 2009-003330
Application 10/801,277
Technology Center 1600

Decided: December 29,2009

Before JAMES T. MOORE, *Vice Chief Administrative Patent Judge,* and DONALD E. ADAMS and FRANCISCO C. PRATS, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134 involves claims 19-30, the only claims pending in this application. We have jurisdiction under 35 U.S.C. § 6(b).

STATEMENT OF THE CASE

The claims are directed to a method of preventing destructive joint disease associated with rheumatoid arthritis in a human individual with an

earlier stage of rheumatoid arthritis (claims 19-22); a method of reducing inflammation associated with rheumatoid arthritis in a human individual with rheumatoid arthritis (claims 23-26); and a method of reducing a level of an interleukin in a human individual with rheumatoid arthritis (claims 27-30). Claims 19, 20, 23, and 27 are illustrative:

19. A method of preventing destructive joint disease associated with rheumatoid arthritis in a human individual with an earlier stage of rheumatoid arthritis comprising: orally administering about 50 I.U./kg to about 25,000 I.U./kg of IFN-α to said individual; and immediately swallowing said IFN-α.

20. The method of claim 19, wherein about 30,000 units of IFN- α is orally administered.

23. A method of reducing inflammation associated with rheumatoid arthritis in a human individual with rheumatoid arthritis comprising: orally administering about 50 I.U./kg to about 25,000 I.U./kg of IFN-α to said individual; and immediately swallowing said IFN-α.

27. A method of reducing a level of an interleukin in a human individual with rheumatoid arthritis, comprising: orally administering about 50 I.U./kg to about 25,000 I.U./kg of IFN-α to said individual; and immediately swallowing said IFN-α, thereby reducing the level of IL-1, IL-6, IL-8, or a combination thereof in said individual.

The Examiner relies on the following evidences:

Cummins	US 4,497,795	Feb. 5, 1985
Cummins, Jr.	US 5,019,382	May 28, 1991

S. Shiozawa, et al., *A Preliminary Study on the Effect of Alpha-interferon Treatment on the Joint Inflammation and Serum Calcium in Rheumatoid Arthritis*, 31 Br. J. Rheum. 405-408 (1992).

M. Javad Aman, et al., *Regulation of Cytokine Expression by Interferon-α in Human Bone Marrow Stromal Cells: Inhibition of Hematopioietic Growth*

Factors and Induction of Interleukin-1 Receptor Antagonist, 84(12) Blood 4142-4150 (1994).

The rejections presented by the Examiner follow:

1. Claims 20, 24, and 28 stand rejected under 35 U.S.C. § 112, second paragraph.

2. Claims 19-22 stand rejected under the enablement provision of 35 U.S.C. § 112, first paragraph.

3. Claims 19-26 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Shiozawa, '795, and '382.

4. Claims 27-30 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Shiozawa, '795, '382, and Aman.

We reverse.

Definiteness:

ISSUE

Has Appellant established error in the Examiner's conclusion that the term "unit" is indefinite?

FINDINGS OF FACT

FF 1. The Examiner finds that "because independent claims 19, 23 and 27 recite international units" it is unclear whether the term "unit" as recited in dependent claims 20, 24, and 28 "should be 'units' or 'international units'" (Ans. 4).

FF 2. The Examiner finds that "it is not clear if the dosage administered [in claims 20, 24, and 26] is per Kg or total dose administered" (*id.*).

FF 3. The Examiner finds that "Appellant uses 'units' and 'international unit' interchangeably"' (Ans. 9).

FF 4. '382 teaches that:

> Interferon of human and murine origins has been quantified in the art in terms of International Units ("IU"). *As used herein*, a "unit" of interferon (to be distinguished from "IU") shall mean the reciprocal of a dilution of interferon-containing material that, as determined by assay, inhibits one-half the number of plaques of a challenge virus, the challenge virus being the vesicular stomatitis virus ("VSV"). So quantified a "unit" of interferon is routinely found to be about one-tenth the quantity of interferon represented by one "IU." In other words, *for the purpose of defining the present invention*, 1 unit ≃ 0.1 IU.

('382, col. 3, ll. 45-56 (emphasis added); *Cf.* Ans. 9.)

FF 5. The Examiner finds that "[t]here is no teaching in the instant specification with respect to the conversion" between the term unit and the term I.U. (Ans. 10).

FF 6. Appellant's Specification discloses that "[a] significant decrease in CD3-mediated IFN-γ secretion was seen post-treatment in normal controls ingesting 30,000 units IFN-α" (Spec. 8: 2-4).

FF 7. Appellant's Specification discloses that "interferon may be administered in a dosage of from about 50 I.U./kg to about 25000 I.U./kg" (Spec. 21: 14-15).

PRINCIPLES OF LAW

Claim language must be analyzed "not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary skill in the pertinent art." *In re Moore*, 439 F.2d 1232, 1235 (CCPA 1971).

Claims are in compliance with 35 U.S.C. § 112, second paragraph, if "the claims, read in light of the specification, reasonably apprise those skilled in the art and are as precise as the subject matter permits." *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385 (Fed. Cir. 1987).

ANALYSIS

The Examiner finds that "Appellant uses 'units' and 'international units' interchangeably"' (FF 3; *see also* Reply Br. 8). Nevertheless, the Examiner finds that "[t]he '382 patent clearly contradicts Appellants [sic] position" by teaching that "1 unit is equivalent [to] 0.1 I.U[.]" (Ans. 9; FF 4). In this regard, the Examiner finds that Appellant's Specification fails to disclose a relationship between, or conversion factor, that is to be used to derive a numeric value for units from international units (I.U.) (*see* FF 5). We are not persuaded.

As Appellant explains, in contrast to the present Specification, '382 limits the definition of the term "unit" to the context of the disclosure in '382 (Reply Br. 7; FF 4). We agree.

Further, Appellant explains "claims 20, 24 and [28] . . . each depend from claims that set forth dosage in International Units. Thus, a person of skill in the art reading the claims in the proper context would understand that

'units' referred to in dependent claims 20, 24, and [28] . . . refers to 'international units'" (App. Br. 8). We agree.

Lastly, we disagree with the Examiner's finding that "it is not clear if the dosage administered is per Kg or total dose administered" (FF 2). Each independent claim requires the oral administration of about 50 I.U./kg to about 25,000 I.U./kg of IFN- α (*see, e.g.,* Claim 19; *see also* FF 7). Each of dependent claims 20, 24, and 28 require the dose of IFN- α to be about 30,000 units. Accordingly, when viewed through the lens of a person of ordinary skill, in light of the teachings of the prior art and Appellant's disclosure, dependent claims 20, 24, and 28 refer to the total dose of IFN- α administered – about 30,000 units (*see generally,* App. Br. 8).

CONCLUSION OF LAW

Appellant established error in the Examiner's conclusion that the term "unit" is indefinite. The rejection of claims 20, 24, and 28 under 35 U.S.C. § 112, second paragraph is reversed.

Enablement:

ISSUE

Has Appellant established error in the Examiner's conclusion that Appellant's Specification fails to provide an enabling disclosure of preventing destructive joint disease associated with rheumatoid arthritis in an individual?

FINDINGS OF FACT

FF 8. Appellant's Specification exemplifies a "Phase I Study" of RA, wherein "all [RA] patients met American College of Rheumatology (ACR) criteria for the diagnosis of RA" (Spec. 77: 17-18).

FF 9. Appellant's Specification discloses that "[e]arly treatment of RA with ingested IFN-α prevents or retards progression of RA via the reduction of inflammatory cytokine production" (Spec. 86: 11-13).

FF 10. Appellant's Specification discloses that:

> The rationale for treatment of RA by ingested IFN-α is that a proportion of RA patients will eventually develop destructive joint disease. The goal of therapy is to provide an agent that is readily accepted by patients, that is non-toxic so that it can be considered for use in the earliest stage of the disease process, is administered frequently without inconvenience, may prevent destructive phase of the disease, and neither induce nor be abrogated by the presence of circulating IFN neutralizing antibodies.

(Spec. 85: 17-24.)

FF 11. The Examiner finds that "Appellant has not disclosed how to use the claimed invention to prevent destructive joint disease associated with rheumatoid arthritis by administering IFN-α orally of [sic] the subjects" (Ans. 5). In this regard, the Examiner finds that there is no evidence in Appellant's "specification or the prior art [(specifically Shiozawa)] to indicate that the administration of interferon alpha prevents destructive joint disease associated with rheumatoid arthritis in an individual" (Ans. 17).

FF 12. The Examiner finds that Appellant's Specification fails to disclose how those patients suffering from RA, but not destructive joint disease associated with RA will be identified (*see* Ans. 5; *see also* Ans. 15). In this

regard, the Examiner finds that Appellant's Specification fails to provide guidance that would allow a person of ordinary skill in the art to identify a phase or stage of rheumatoid arthritis that may occur before the onset of destructive joint disease (Ans. 16).

FF 13. The Examiner finds that Appellant's Specification fails to provide a working example that describes the prevention of destructive joint disease (Ans. 5).

FF 14. The Examiner finds that while "example 37 [of Appellant's Specification] indicates 'a trend toward inhibition of CD3- and Con A-mediated IL-1, IL-6, and IL-8 secretion after eight weeks,' of treatment with orally ingested IFN-α . . . none of these indices are correlated with destructive joint disease prevention"' (Ans. 17). To the contrary, the Examiner finds that "these indices are related to the management [of] rheumatoid arthritis" (*id.*).

PRINCIPLES OF LAW

"In order to satisfy the enablement requirement of section 112, an applicant must describe the manner of making and using the invention 'in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use the same . . .' 35 U.S.C. § 112, para. 1."' *Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318, 1323 (Fed. Cir. 2005).

> Factors to be considered in determining whether a disclosure would require undue experimentation … include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the

> predictability or unpredictability of the art, and (8) the breadth of the claims.

In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988). However, as set forth in *Enzo Biochem, Inc., v. Calgene, Inc.*, 188 F.3d 1362, 1371 (Fed. Cir. 1999) "the *Wands* factors 'are illustrative, not mandatory. What is relevant depends on the facts.' [citation omitted]." In this regard, we note that working examples are not required to satisfy 35 U.S.C. § 112, first paragraph. *In re Strahilevitz*, 668 F.2d 1229, 1232 (CCPA 1982).

The Examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. *See In re Wright*, 999 F.2d 1557, 1561-62 (Fed. Cir. 1993). (Examiner must provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure).

ANALYSIS

The Examiner concludes that Appellant's Specification fails to provide an enabling description of the claimed method "of preventing destructive joint disease associated with rheumatoid arthritis without an undue amount of experimentation because the specification and the prior art have not prevented destructive joint disease associated with rheumatoid arthritis by administering IFN-α orally" (Ans. 4-5).

Appellant contends that "RA patients can be identified that do not yet have destructive joint disease, and only prevention of destructive joint disease as claimed need be enabled" (App. Br. 11). We agree. Claim 19 is drawn to a method of preventing destructive joint disease associated with RA in a human individual with an earlier stage of RA (Claim 19). Claims

20-22 depend directly from claim 19. We interpret the phrase "an earlier stage of rheumatoid arthritis" to mean a stage of rheumatoid arthritis that occurs prior to the onset of destructive joint disease (*see* FF 10 ("[t]he goal of therapy is to provide an agent that is readily accepted by patients . . . for use in the earliest stage of the disease process")).

Appellant contends that the Specification establishes a distinction between destructive joint disease and RA, identifies the patient population as "RA sufferers who have not yet reached the destructive phase of RA, *i.e.,* destructive joint disease", and that a person of ordinary skill in the art can identify these patients "by the ACR criteria for diagnosis of RA" (App. Br. 12; FF 8-10). We agree.

The Examiner failed to establish an evidentiary basis on this record to support a conclusion that a person of ordinary skill in this art would not be able to identify individuals in an early stage of RA by use of diagnostic criteria such as the ACR criteria for diagnosing RA.

We recognize the Examiner's reliance on Shiozawa to establish the state of the art at the time of Appellant's filing date (*see* FF 11). Shiozawa, however, is silent with regard to destructive joint disease (*id.*). Therefore Shiozawa fails to inform this record of the state of the art relative to destructive joint disease. At best, Shiozawa is neutral with regard to Appellant's claimed invention.

We also recognize the Examiner's finding that Appellant's Specification fails to provide a working example that describes the prevention of destructive joint disease (FF 13). We note, however, that working examples are not required to satisfy 35 U.S.C. § 112, first paragraph. *Strahilevitz*, 668 F.2d at 1232. Nevertheless, we recognize the

Examiner's finding that Example 37 of Appellant's Specification indicates a trend toward the inhibition of inflammatory cytokine production in RA patients treated with orally ingested IFN-α (FF 14). According to Appellant's Specification the "[e]arly treatment of RA with ingested IFN-α prevents or retards progression of RA via the reduction of inflammatory cytokine production" and thereby prevent the destructive phase of the disease (FF 9-10). Accordingly, we are not persuaded by the Examiner's conclusion that Appellant's Specification fails to provide an enabling disclosure of the claimed invention.

In sum, Appellant contends that a proportion of RA patients develop destructive joint disease, that these patients who are in the early stage of rheumatoid arthritis but not suffering from destructive joint disease can be identified, and that the early treatment of RA with ingested IFN-α prevents or retards progression of RA, including the destructive phase of RA (App. Br. 12; FF 8-10). For the foregoing reasons we find that Appellant's Specification supports this contention.

CONCLUSION OF LAW

Appellant established error in the Examiner's conclusion that Appellant's Specification fails to provide an enabling disclosure of preventing destructive joint disease associated with rheumatoid arthritis in an individual.

The rejection of claims 19-22 under the enablement provision of 35 U.S.C. § 112, first paragraph is reversed.

Obviousness:

PRINCIPLES OF LAW

[T]he [E]xaminer bears the initial burden, on review of the prior art or on any other ground, of presenting a prima facie case of unpatentability." *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992). On appeal to this Board, Appellant must show that the Examiner has not sustained the required burden. *See Ex parte Yamaguchi*, 88 USPQ2d 1606, 1608 and 1614 (BPAI 2008) (precedential); *Ex parte Fu*, 89 USPQ2d 1115, 1118 and 1123 (BPAI 2008) (precedential).

"The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007).

> When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that is was obvious under § 103.

Id. at 421. It is proper to "take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *Id.* at 418. *See also id.* at 421 ("A person of ordinary skill is also a person of ordinary creativity, not an automaton."). In sum, the "suggestion test is in actuality quite flexible and not only permits, but requires, consideration of common knowledge and common sense." *DyStar Textilfarben GmbH v. C.H. Patrick Co.*, 464 F.3d 1356, 1367 (Fed. Cir. 2006).

Nevertheless, an invention "composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. . . . [I]t can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007).

The combination of Shiozawa, '795, and '382:

While Appellant does not separately group the claims, we find that Appellant provides separate arguments for each independent claim. Accordingly, we have considered the claims as they related to the following groups: (I) claims 19-22 and (II) claims 23-26.

Claim 19:

ISSUE

Has Appellant established error in the Examiner's conclusion that the prior art treats or suggests treating the same patient population as is required by Appellant's claimed invention?

FINDINGS OF FACT

FF 15. Appellant's Specification discloses that:

> The rationale for treatment of RA by ingested IFN-α is that a proportion of RA patients will eventually develop destructive joint disease. The goal of therapy is to provide an agent that is readily accepted by patients, that is non-toxic so that it can be considered for use in the earliest stage of the disease process, is administered frequently without inconvenience, may prevent destructive phase of the disease, and neither induce nor be

> abrogated by the presence of circulating IFN neutralizing antibodies.

(Spec. 85: 17-24.)

FF 16. Shiozawa performed a "12-week, double-blind trial comparing α-interferon and placebo in patients with rheumatoid arthritis fulfilling the ARA [(American Rheumatism Association)] diagnostic criteria" (Shiozawa 405: col. 1, ll. 35-37).

FF 17. The Examiner finds that Shiozawa "teaches that interferon-alpha therapy improves certain inflammatory indices of rheumatoid arthritis such as the joint score, C-reactive protein value and platelet count . . . [t]hus treating the destructive joint disease associated with rheumatoid arthritis" (Ans. 6).

FF 18. The Examiner finds that '795 teaches the oral administration of "about 500 to 5000 IU/Kg" of IFN-α (Ans. 6).

FF 19. We note, however, that '795 teaches the use of IFN-α to regulate the appetite of a warm-blooded vertebrate not the treatment of RA (*see generally* '795, Abstract). In this regard, '795 teaches that "[t]he amounts of interferon effective to modulate food intake have been discovered to be *much lower than* those amounts of interferon necessary to realize its antiviral, antitumor, and modulatory effects" ('795, col. 3, ll. 51-54 (emphasis added)).

FF 20. The Examiner finds that '382 teaches the treatment of "rheumatoid arthritis (see column 5, lines 40-50)" (Ans. 7).

FF 21. '382 teaches that "[i]t is critical that the interferon be administered in a dosage form adapted to assure maximum contact of the interferon in said

dosage form with the oral and pharyngeal mucosa of the human or animal undergoing treatment" ('382, col. 4, ll. 37-41).

FF 22. '382 exemplifies the treatment of individuals with "*acute* rheumatoid arthritis" ('382, col. 12, l.15 (emphasis added)).

FF 23. '382 teaches that "[r]heumatoid arthritis patients are pain free within 2 to 10 days of initiating treatment in accordance with . . . ['382's] invention. However, treatment of that disease is preferably conducted by administration of interferon for up to about three (3) months" ('382, col. 5, 46-50).

FF 24. The Examiner finds that "treating rheumatoid arthritis with interferon alpha will inherently prevent destructive joint disease" (Ans. 21).

ANALYSIS

Claim 19 is drawn to a method of preventing destructive joint disease associated with RA in a human individual with an earlier stage of RA (Claim 19). Claims 20-22 depend directly from claim 19.

As discussed above, we interpret the phrase "an earlier stage of rheumatoid arthritis" to mean a stage of rheumatoid arthritis that occurs prior to the onset of destructive joint disease (FF 10).

The method of claim 19 comprises the oral administration and immediate swallowing of about 50 I.U./kg to about 25,000 I.U./kg of IFN-α (Claim 19).

We interpret the phrase "immediately swallowing" to mean that no, or an insignificant amount of, IFN-α is adsorbed through the oral and pharyngeal mucosa prior to swallowing the administered IFN-α (*Cf.* FF 21). In addition, we interpret this phrase to modify the dosage that is

administered to the individual. Specifically, we interpret the claim to require that each individual dose administered to the individual contains about 50 I.U./kg to about 25,000 I.U./kg of IFN-α.

Shiozawa teaches the treatment of RA patients that fulfill the ARA diagnostic criteria (FF 16). The Examiner, however, failed to establish that patients meeting the diagnostic criteria established by the ARA have an "earlier stage of rheumatoid arthritis" as required by Appellant's claim 19 (*see* App. Br. 17). The same is true of '382. The Examiner failed to establish that '382 suggests the administration of IFN-α to a human with an earlier stage of RA as required by Appellant's claim 19. In this regard, we recognize '382's exemplification of the administration of IFN-α to patients with acute RA; which is, by definition, not an early stage of RA (FF 22).

'795's use of IFN-α to regulate the appetite of a warm-blooded vertebrate (FF 19) fails to overcome the deficiencies in Shiozawa and '382. While the Examiner relies upon '795 to teach the oral administration of an IFN-α dosage within the scope of Appellant's claimed invention, the Examiner failed to provide an evidentiary basis to support a conclusion that a person of ordinary skill in this art would have recognized that the dosage required to modulate appetite in a warm-blooded vertebrate, as taught by '795, would be effective to prevent destructive joint disease associated with rheumatoid RA in a human individual with an earlier stage of rheumatoid arthritis as required by claim 19 (*Cf.* FF 19 (the oral administration to the gut of an IFN-α dosage that is "effective to modulate food intake have been discovered to be *much lower than* those amounts of interferon necessary to realize its antiviral, antitumor, and modulatory effects")).

CONCLUSION OF LAW

Appellant established error in the Examiner's conclusion that the prior art treats or suggests treating the same patient population as is required by Appellant's claimed invention.

The rejection of claims 19-22 under 35 U.S.C. § 103(a) as unpatentable over the combination of Shiozawa, '795, and '382 is reversed.

Claim 23:

ISSUE

Has Appellant established error in the Examiner's conclusion that the prior art suggests a method of reducing inflammation associated with RA in a human with RA by orally administering and immediately swallowing IFN-α in an amount of about 50 I.U./kg to about 25,000 I.U./kg?

ANALYSIS

Claim 23 is drawn to a method of reducing inflammation associated with RA in a human with RA (Claim 23). The method of claim 23 comprises the oral administration and immediate swallowing of about 50 I.U./kg to about 25,000 I.U./kg of IFN-α (*id.*). Claims 24-26 depend directly from claim 23.

Appellant contends that "the levels taught in the '795 [patent] for appetite stimulation were too low to have other therapeutic effects" (App. Br. 18; FF 19).

Neither Shiozawa nor '382 teach the oral administration and immediate swallowing of IFN-α in an amount of about 50 I.U./kg to about 25,000 I.U./kg. '795's use of IFN-α to regulate the appetite of a warm-

blooded vertebrate (FF 19) fails to overcome the deficiencies in Shiozawa and '382. While the Examiner relies upon '795 to teach the oral administration of an IFN-α dosage within the scope of Appellant's claimed invention, the Examiner has failed to provide an evidentiary basis to support a conclusion that a person of ordinary skill in the art would have recognized that the '795 dosage amount to modulate appetite in a warm-blooded vertebrate would be effective to reduce inflammation associated with rheumatoid arthritis in a human as required by claim 23 (*Cf.* FF 19).

CONCLUSION OF LAW

Appellant established error in the Examiner's conclusion that the prior art suggests a method of reducing inflammation associated with RA in a human with RA by orally administering and immediately swallowing IFN-α in an amount of about 50 I.U./kg to about 25,000 I.U./kg. The rejection of claims 23-26 under 35 U.S.C. § 103(a) as unpatentable over the combination of Shiozawa, '795, and '382 is reversed.

The combination of Shiozawa, '795, '382, and Aman:

ISSUE

Has Appellant established error in the Examiner's conclusion that the prior art suggests a method of reducing a level of an interleukin in a human with RA by orally administering and immediately swallowing IFN-α in an amount of about 50 I.U./kg to about 25,000 I.U./kg?

FINDINGS OF FACT

FF 25. The Examiner relies on Shiozawa, '795, and '382 as discussed above (Ans. 7).

FF 26. The Examiner finds that Shiozawa fails to "teach the reduction of interleukins following oral administration of interferon alpha" (Ans. 8).

FF 27. The Examiner relies on Aman to teach "the reduction of interleukin-1 following the administration of [i]nterferon alpha" (*id.*).

FF 28. Aman does not teach or suggest the oral administration and swallowing of a dosage of IFN-α to a human with RA. Instead, Aman's work is limited to tissue culture.

ANALYSIS

Claim 27 is drawn to a method of reducing a level of an interleukin in a human with RA (Claim 27). The method of claim 27 comprises the oral administration and immediate swallowing of about 50 I.U./kg to about 25,000 I.U./kg of IFN-α (*id.*). Claims 28-30 depend directly from claim 27.

Appellant contends that "Aman's teaching is limited to tissue cultures" (App. Br. 21; FF 28). In addition, Appellant contends that Aman would not lead a person of ordinary skill in the art to the oral administration and swallowing of a specific dosage of IFN-α as required by Appellant's claimed invention (*see* Reply Br. 14). We agree.

Aman fails to make up for the deficiencies in the combination of Shiozawa, '795, and '382 as discussed above.

CONCLUSION OF LAW

Appellant established error in the Examiner's conclusion that the prior art suggests a method of reducing a level of an interleukin in a human with RA by orally administering and immediately swallowing IFN-α in an amount of about 50 I.U./kg to about 25,000 I.U./kg. The rejection of claims 27-30 under 35 U.S.C. § 103(a) as unpatentable over the combination of Shiozawa, '795, '382, and Aman is reversed.

REVERSED

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